

Serial No.: 10/054,447

Confirmation No.: 5485

Filed: January 22, 2002

For: METHOD FOR COATING MEDICAL DEVICE SURFACES

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**Remarks**

The Final Office Action mailed June 5, 2007 has been received and reviewed. Claims 1, 233, 278 and 279 having been amended, claim 277 having been canceled herein, and claims 293-298 having been added, the pending claims are claims 1-10, 233, 273-276, 278-281 and 293-298, all of which are currently under consideration by the Examiner.

**Examiner Interview**

Applicants thank the Examiner for the courtesy of a telephone interview on August 21, 2007, during which the specification, the then-pending claims, and the prior art were discussed.

**Cancelled Claims**

Claim 277 has been cancelled. The elements of claim 277 have been incorporated into independent claim 233.

**Amended Claims**

Claims 1, 233, 278 and 279 have each been amended.

Claim 1 has been amended to explicitly recite the method steps of providing the medical device with the catechol moiety on the surface and thereafter coating the medical device with the hydrophilic polymer.

Support for this amendment can be found throughout the specification, including for example at page 9, line 25 –page 10, line 3. The method includes “chemically binding under appropriate conditions a hydrophilic polymer to a biomaterial surface.”; “The hydrophilic polymer comprises . . . a guanidine moiety” and “The biomaterial surface comprises . . . a catechol moiety.”

Claim 233 has been amended to incorporate the limitations of claim 277, which was objected to as being dependent upon a non-allowed claim.

No new matter has been added.

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Claim 278 has been amended to change dependency based on the amendments to claims 233 and 279.

No new matter has been added.

Claim 279 has been amended and redrafted in independent form to incorporate the limitations of previous claim 233.

No new matter has been added.

**New Claims**

New claims 293-298 have been added to claim certain preferred embodiments of the invention. These claims depend upon claim 279 which has been rewritten to be in independent form. Claims 293-298 mirror dependent claims 273-276, 280 and 281 which depend from amended claim 233.

No new matter has been added.

**Rejections under 35 U.S.C. §112, Second Paragraph**

The Examiner rejected claims 1-10, 276, and 280-281 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 1 has been amended to specifically recite that the medical device having the catechol moiety disposed on the surface thereof is provided and thereafter coated with the hydrophilic polymer. Thus, Applicants respectfully submit that the rejection has been rendered moot.

Finally, the Examiner has alleged that claims 9-10 and 280-281 do not further limit claims 1 and 233, respectively. Applicants respectfully traverse the rejection.

The Supreme Court has long held that the primary purpose of requiring definiteness in claim language is to give fair warning to persons in the art of what would constitute infringement. United Carbon Co. v. Binney Co., 317 U.S. 328, 87 L. Ed. 32, 63 S. Ct. 165

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(1942). Hence, the appropriate legal standard is whether the claims, read in light of the specification, reasonably apprise those skilled in the art of the scope of the invention. Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 USPQ 81 (1986). However, the specification and prosecution history are relevant in determining whether a specific term has a definite meaning. See All Dental Prodx, LLC v. Advantage Dental Products, Inc., 64USPQ2d 1945 (Fed. Cir. 2002).

Applicants respectfully submit that claims 9-10 and 280-281 further limit claims 1 and 233, respectively. For example, because neither claim 1 nor claim 233 explicitly recites a primer, and claims 9-10 and 280-281 each recite a primer, claims 9-10 and 280-281 further limit claims 1 and 233, respectively. The Specification clearly intends a primer coating on a surface of the device to be optional. See, for example, page 10, lines 24-25 and page 25, line 26 – page 27, line 4. One of skill in the art would readily recognize from the specification that a primer coating is an optional element of the invention, and that a catechol moiety could exist on the surface of the medical device with or without the presence or application of a primer coating.

In view of the amendments and remarks presented herein, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, are respectfully requested.

**Rejection under 35 U.S.C. §102**

The Examiner rejected claims 1-5, 7, 9-10, 233-276, 278, and 280-281 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent 6,818,018 (“Sawhney”).

Sawhney “relates generally to the in situ formation of hydrogels, and more specifically, to compositions of hydrogels that are formed in situ by a combination of physical and chemical crosslinking” (column 1, lines 5-8). As noted by the Examiner, Sawhney recites “poly(guanidine)” as one example among many of water soluble polymers that can be used to form the hydrogels (column 12, line 21).

In one embodiment, Sawhney discloses that “[t]he in situ formed hydrogels of the present invention further may be applied in conjunction with bioactive molecules that either are

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dissolved or dispersed within the hydrogels" (column 15, line 66 to column 16, line 2), and recites "dopamine" as one example among many of suitable biologically active agents (e.g., column 17, line 46).

In another embodiment, Sawhney discloses that "such hydrogels also may be used to coat other types of implants for long-term use in the body, such as catheters, cannulas, bone prostheses, cartilage, replacements, mini pumps and other drug delivery devices, artificial organs and blood vessels, meshes for tissue reinforcement, etc. Hydrogel compositions also may be used to coat platinum wires, which then are administered to the site of an aneurysm via catheter. Such surface treatment renders the implants nonimmunogenic and reduces the incidence of foreign body reaction." (Column 19, lines 27-36).

Applicants assert that Sawhney fails to disclose, teach or suggest, the specific method steps claimed in amended independent claim 1, or the materials as claimed in amended claims 233 and 279. Specifically, Sawhney fails to disclose, teach or suggest a) providing a medical device having a catechol moiety disposed on the surface of said device; and thereafter b) coating the medical device having the catechol moiety disposed on the surface thereof with a hydrophilic polymer comprising a guanidinato moiety to form a chemical bond between the guanidino moiety of the hydrophilic polymer and the catechol moiety of the medical device surface. The hypothetical polymer of Sawhney as containing items chosen from separate lists in the disclosure would have a catechol moiety and a guanidine moiety prior to any application of the polymer to a medical device surface.

For at least this reason, Applicants respectfully submit that claims 1-5, 7 and 9-10 are not anticipated by Sawhney and request that the rejection be withdrawn.

Claim 233 has been amended to incorporate the limitations of dependent claim 277, which was objected to as being dependent upon a rejected claim. This amendment makes the rejection of claim 233 moot. For at least this reason, Applicants respectfully submit that claims 233, 273-276, 280 and 281 are not anticipated by Sawhney and request that the rejection be withdrawn.

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Claim 278 was amended to be dependent upon claim 279, which has been rewritten in independent form since it was objected to as being dependent upon a rejected claim. For at least this reason, Applicants respectfully submit that claim 278 is not anticipated by Sawhney and request that the rejection be withdrawn.

Reconsideration and withdrawal of all rejections under 35 U.S.C. §102 are respectfully requested.

**Equivalents**

The amendments to the claims and the arguments presented in supplemental response to the Final Office action have been made to claim subject matter which the Applicants regard as their invention. By such amendments, the Applicants in no way intend to surrender any range of equivalents beyond that which is needed to patentably distinguish the claimed invention as a whole over the prior art. Applicants expressly reserve patent coverage to all such equivalents that may fall in the range between applicants literal claim recitations and those combinations that would have been obvious in view of the prior art. In particular, as noted above, many of the claims have not been narrowed within the meaning of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 62 USPQ2d 1705 (2002), and Applicants are therefore entitled to the full range of equivalents with respect to each of the presently-pending claims.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

The Examiner is hereby authorized to charge the fees required in connection with this Amendment to Deposit Account No.13-2546, in accordance with the Transmittal submitted herewith. The Examiner is also authorized to debit any other fees required in connection with this application, or to credit any overpayment of fees in connection with this application to Deposit Account No. 13-2546.

**Amendment and Response**

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